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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,551

04/10/2006

Yukio Nagasaki

2006-0538A

8962

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WASHINGTON, DC 20006-1021

EXAMINER

HAQ, SHAFIQUL

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

09/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,551	Applicant(s) NAGASAKI ET AL.	
	Examiner SHAFIQL HAQ	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicants' election of species filed 13 June 2008 in response to Office Action dated 15 May 2008 is acknowledged and entered. Claims 1 and 6-10 read on the elected species. Because applicant did not distinctly and specifically present the reasons for traversal, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, the restriction requirement is deemed proper and is made FINAL.
2. Accordingly, Claims 2-5 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
3. Claims 1 and 6-10 are examined on merits.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 1 and 9 recite the term "residue". The term "residue" is not defined in the specification. The plain dictionary meaning for the term "residue" is something that remains after a part is taken, separated, or designated or after the completion of a process. Therefore, a residue of a protein or a receptor can be an amino acid. A

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residue of a specific binding partner (i.e. of a nucleic acid) can be a nucleotide or a nucleoside. Therefore, it is unclear what Applicants are intended to encompass by the term "residue".

7. Claim 1 recites "agglutination reaction is conducted under a condition under which fine particles whose chargeable group is in a charged state" in lines 9-10. The condition under which chargeable group remains in charged state have not been described in the specification and thus it is unclear what conditions are encompassed by the "condition" as claimed in claim 1.
8. Claim 1 is a method to detect an analyte in an aqueous solution with the use of agglutination reaction of polymer-based fine particles but however, the claim does not clearly define positive steps in carrying out the method of detection. As for example, the method does not have a positive step of contacting an analyte with the polymer-based fine particle and does not have a positive step of detection of the agglutinated matter which remains after treatment with a condition under which bond made by electrostatic bond is cleaved but not the biologically specific bond.
9. With regard to claim 6, it is unclear whether "n" represents number of oxygen of number of $\text{CH}_2\text{CH}_2\text{O}$ group? It seems that a parenthesis is missing. Proper correction is required.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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11. Claims 1 and 6-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Step (b) of claim 1 recites the following in the last three lines: "agglutinated matter is treated under a condition under which, although the biologically specific bond between fine particles is not cleaved, the bond made by electrostatic interaction can be cleaved". The only conditions described in the specification is by adjusting the concentration of salt (NaCl, Na₂CO₃, Na₂SO₄ etc.) to 0.1 to 2M (page 14, lines 3-6 and Example 1 of specification). As articulated, the claim encompasses various conditions, which at least may include change in pH, heat, pressure that may influence electrostatic interaction and dissociation but however, in the specification there is no mention of these conditions or any other conditions (except salt concentration) or written description or guidance for any other conditions except for the condition of salt concentration.

Therefore, an artisan in the art would not be able to practice the invention because an undue experimentation will be required to judge the suitability of other conditions encompassed by the term "condition" of claim 1. Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art;

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relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Shafiqul Haq/
Examiner, Art Unit 1641